UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF NEW YORK

SHARON BLACK & MAX BLACK,

Plaintiffs,

v.

COVIDIEN, PLC, et al.,

Defendants.

Case # 17-CV-6085-FPG

DECISION AND ORDER

INTRODUCTION

On January 26, 2018, this Court dismissed Plaintiffs Sharon Black and Max Black's ("Plaintiffs") product liability suit against Medtronic Inc. ("Defendant"). ECF No. 10. On February 9, 2018, Plaintiffs filed their First Amended Complaint ("FAC") bringing negligence, design defect, failure to warn, and loss of consortium claims. ECF No. 11. On February 22, 2018, Defendant moved to dismiss Plaintiffs' failure to warn claim. ECF No. 12. In its response to Defendant's Motion to Dismiss, Plaintiffs asked the Court to impose sanctions on Defendant's attorney under Rule 11. ECF No. 16. For the reasons stated below, Defendant's Motion to Dismiss is DENIED. Additionally, the Court DENIES Plaintiffs' request for sanctions.

BACKGROUND[1]

Although the Court assumes the parties' familiarity with the facts and history of this case, a brief summary follows. Plaintiff Sharon Black's physician implanted a piece of Defendant's Parietex Composite mesh to repair Plaintiff's hernia on October 1, 2009. On December 9, 2013, doctors removed Plaintiff's stomach because it was damaged. Plaintiffs' initial Complaint based

[1] The following facts are taken from this Court's previous order, ECF No. 10.

on this incident alleged that "small pore surgical mesh products" such as Parietex "generally induce a greater inflammatory response in host[s] than large pore surgical mesh products," and that the risk "of an adverse reaction to any surgical mesh product increases with the increase in the host's inflammatory response." ECF No. 2-2 at 10. The Court dismissed Plaintiffs' negligence and design defect claims because their Complaint had not provided "facts indicating that the Parietex mesh actually played any role in Mrs. Black's injury." ECF No. 10 at 3.

The initial Complaint also raised a failure to warn claim, alleging that Defendant "failed to adequately warn Plaintiff or Plaintiff's physician(s) . . . of the risks of Parietex." ECF No. 2-2 at 19. The Court dismissed this claim because Plaintiffs did "not identify what warnings Defendant gave to Mrs. Black's physicians, how they were inadequate, or what warnings should have been given." ECF No. 10 at 6.

Plaintiffs' FAC supplements their initial failure to warn claim with additional facts. Specifically, Plaintiffs allege that Defendant did not disclose to Ms. Black and her physicians how Parietex's design "increased the risk of inflammation resulting in an increased risk of mesh migration and injury to surrounding organs" and that Ms. Black would not "have had Parietex implanted in her" had she known of this risk. ECF No. 11 at 18. Defendant again moves to dismiss Plaintiffs' failure to warn claim because "the Amended Complaint fails to identify any warning allegedly given or specifying how a given warning was allegedly deficient." ECF No. 17 at 5.

DISCUSSION

I. Legal Standard

Federal Rule of Civil Procedure 12(b)(6) provides that a party may move to dismiss a complaint for "failure to state a claim upon which relief can be granted." Fed. R. Civ. P. 12(b)(6). In reviewing a motion to dismiss, a court "must accept as true all of the factual allegations

contained in the complaint," *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 572 (2007), and "draw all reasonable inferences in Plaintiff's favor." *Faber v. Metro. Life Ins. Co.*, 648 F.3d 98, 104 (2d Cir. 2011). To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to "state a claim to relief that is plausible on its face." *Twombly*, 550 U.S. at 570. These factual allegations "must be enough to raise a right to relief above the speculative level," *id.* at 545, and "allow[] the court to draw the reasonable inference that the defendant is liable for the misconduct alleged." *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009).

II. Failure to Warn

To succeed on a failure to warn claim, a plaintiff must prove that "(1) a manufacturer has a duty to warn (2) against dangers resulting from foreseeable uses about which it knew or should have known, and (3) that failure to do so was the proximate cause of the harm." *State Farm Fire & Cas. Co. v. Nutone, Inc.*, 426 F. App'x 8, 10 (2d Cir. 2011) (summary order) (citing *Liriano v. Hobart Corp.*, 92 N.Y.2d 232, 237 (1998)). In New York, the manufacturer satisfies its duty to warn of a product's risks "by providing information to the prescribing physician, not to the patient directly." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 284 (S.D.N.Y. 2009). The court should dismiss a failure to warn claim if "a plaintiff does not plead facts indicating how the provided warnings were inadequate." *Reed v. Pfizer, Inc.*, 839 F. Supp. 2d 571, 575 (E.D.N.Y. 2012).

Unlike Plaintiffs' initial Complaint, which did not specify beyond a conclusory level how Defendant's warning about Parietex was inadequate, their FAC specifically alleges that the warnings accompanying the product did not disclose "the risk of inflammation resulting in an increased risk of mesh migration and injury to surrounding organs." ECF No. 11 at 17. Defendant

argues that this factual allegation "barely change[s]" Plaintiffs' "failure to warn allegations." ECF No. 17 at 5.

Defendant understates the difference between the failure to warn claim in the initial Complaint and that in the FAC. Whereas the initial Complaint failed to identify "what warnings Defendant gave to Mrs. Black's physicians, how they were inadequate, or what warnings should have been given," the FAC does not suffer from the same deficiencies. The FAC clarifies the original Complaint by identifying specific warnings related to inflammation and mesh migration that Defendant failed to disclose to Ms. Black and her physician. Additionally, Plaintiff alleged that she would not have consented to the use of Parietex mesh had she known of these risks. The veracity and merit of these allegations will be resolved at later stages of this litigation, but they suffice to survive Defendant's Motion to Dismiss. *See Ward v. Argon Med. Devices*, 5:17-CV-607, 2018 WL 1441314, at *5 (N.D.N.Y. Mar. 22, 2018) (holding that plaintiff's allegations that "defendants' failure to provide adequate warnings to their medical providers indicating that the devices created a risk of serious and dangerous side effects, including but not limited to, the migration of the filter to other parts of the IVC, heart or other organs" stated a failure to warn claim); *Richards v. Johnson & Johnson*, 5:17-cv-178 (BKS/ATB), 2018 WL 2976002, at *4 (N.D.N.Y. June 12, 2018) ("Contrary to [defendant's] contention, the Amended Complaint identifies the absence of a warning regarding the risk of device migration. [Defendant's] citations are inapposite because, in those cases, the plaintiffs failed to identify what information was supposedly missing from the defendants' warnings."). Defendant's Motion to Dismiss is therefore denied.

III. Sanctions

In their response to Defendant's Motion to Dismiss, Plaintiffs claim that Defendant's "Motion goes to great lengths to misrepresent the contents of the Amended Complaint while skipping over the very factual allegations that are the bases of Plaintiffs' Failure to Warn claim and proximate causation" and that under "these circumstances, sanctions [under Rule 11] are appropriate and Plaintiffs' counsel will be pursuing them doggedly." ECF No. 16 at 4. However, Plaintiffs' attorney, despite his assertions to the contrary, neglected to comply with Rule 11 in requesting sanctions. Rule 11 requires parties to serve a motion for sanctions on the other party before presenting it to the court. After the party serves the motion, the other party has 21 days to "withdraw[] or appropriately correct[]" the "challenged paper." Fed. R. Civ. P. 11(c)(2). If the other party does not act in 21 days, only then may the party moving for sanctions present its motion to the court. *Id.*

Plaintiffs' attorney contacted Defendant's attorney via email asking them to withdraw their Motion to Dismiss, ECF No. 17, but such an "informal warning in the form of a letter without service of a separate Rule 11 motion is not sufficient to trigger the 21-day safe harbor period" in the Second Circuit. *Star Mark Mgmt., Inc. v. Koon Chun Hing Kee Soy & Sauce Factory, Ltd.*, 682 F.3d 170, 175 (2d Cir. 2012); *but see Nisenbaum v. Milwaukee Cnty.*, 333 F.3d 804, 808 (7th Cir. 2003) (holding that party's letter to opposing counsel constituted substantial compliance with Rule 11). Accordingly, the Court cannot consider Defendant's request for sanctions and, in any event, does not see any basis for sanctioning Defendant's attorney under Rule 11.

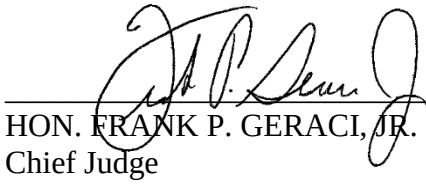
CONCLUSION

For the reasons stated, Defendant's Motion to Dismiss (ECF No. 12) and Plaintiffs' request for sanctions (ECF No. 16) are DENIED.

By separate order, this case will be referred to a United States Magistrate Judge for pretrial proceedings. Defendant must serve its answer to Plaintiffs' FAC by July 17, 2018. Fed. R. Civ. P. 12(a)(4)(A).

IT IS SO ORDERED.

Dated: July 2, 2018
Rochester, New York



HON. FRANK P. GERACI, JR.
Chief Judge
United States District Court